

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Koii Yamada, et al.

Serial No.

10/571,861

Filed: March 14, 2006

For: NOVEL INDOLOPYRROLOCARBAZOLE DERIVATIVE

WITH ANTITUMOR ACTIVITY

Examiner:

Art Unit:

To be determined

To be determined

Commissioner for Patents . P.O. Box 1450

Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR 1.97**

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.



INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 P.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited

by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

	RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE	
If this is inconvenient, additional copies will be submitted up	oon request.		
6. In accordance with 37 C.F.R. 1.97, (check one)			
the attached information is filed within three months of t	he filing date of the captioned case.		
the attached information is filed more than three months Office Action on the merits.	s after the filing date but prior to the	mailing of a first	
the attached information is filed before the mailing of a examination under §1.114.	first Office action after the filing of a	request for continued	
the attached information is being filed more than three rolling of the Mailing date of	of a Final Action, Notice of Allowand aclosed authorization is therefore give	e, or an action that	
each item of information contained in this Information D from a foreign patent office in a counterpart foreign app Statement.			
each item of information contained in the information di from a foreign patent office in a counterpart application designated in §1.56(c) more than thirty days prior to the	and this communication was not red	ceived by any individu	
no item of information contained in this Information Disc foreign patent office in a counterpart foreign application after making reasonable inquiry, was known to any indi- months prior to the filing of this Statement.	, and, to the knowledge of the perso	n signing the certifica	
	Respectfully submitted,		
•		TARI	
	By: David A. Muthard	. ,	
	Attorney For Ap	plicant(s)	
	Reg. No. <u>35,297</u>		
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	Date: 4/30/0	6	



Art Unit:

Examiner:

To be determined

To be determined



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Koji Yamada, et al.

Serial No.: 10/571,861 Case No.: BY0028P

Filed: March 14, 2006

For: NOVEL INDOLOPYRROLOCARBAZOLE

DERIVATIVE WITH ANTITUMOR ACTIVITY

Commissioner of Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

EXPLANATION OF RELEVANCE OF NON-ENGLISH DOCUMENTS UNDER 37 C.F.R. 1.98(a)(3)(i)

Sir:

Applicants respectfully note that three (3) of the documents listed on the USPTO 1449 for submitted herewith is not in the English language and a copy of an English translations of that documents is not within the possession, custody or control of Applicants, and, to the Applicants knowledge, is not readily available. Below is a concise explanation of the relevance of those non-English documents:

The Japanese patent publication JP 6-128283 discloses preparation of a series of 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having a substituted amine substituent on the amine of the fused carbazole dione ring. The compounds disclosed therein are described as anti-tumor compounds. There is no specific disclosure in the JP 6-128283 publication of pyridylalkylamine, furylalkylamine or thienylalkylamine substituents on the amine of the fused carbazol dione ring.

The PCT patent publication WO96/04293 discloses preparation of a series of 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having a substituted amine substituent on the amine of the fused carbazole dione ring. The compounds disclosed therein are described as anti-tumor compounds. There is no specific disclosure in the WO96/04293 publication of pyridylalkylamine, furylalkylamine or thienylalkylamine substituents on the amine of the fused carbazol dione ring.

The Japanese patent publication JP 10-245390 discloses preparation of a series of 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having a substituted

aryl/heteroaryl alkylamine substituent on the amine of the fused carbazole dione ring. The substituted aryl/heteroaryl group is selected from substituted phenyl, substituted pyridyl, substituted furyl, substituted naphthyl and substituted thienyl. The compounds disclosed therein are described as anti-tumor compounds.

The instant invention discloses novel 5H-indolo[2,3-a]pyrrolo[3,4-c]carbazol-5,7(6H)-dione compounds having substituted and unsubstitutued aryl/heterocyclyl alkoxy/alkyl/alkyl amino substituents on the amine of the fused carbazol dione ring. Several classes of such substituents are specifically excluded from the scope of the generic claims.

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VIRGINIA 22313-1450, ON THE DATE APPEARING BELOW.

MERCK & CO., INC.

Respectfully submitted,

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Date: November 30, 2006



Main Claim of the Japanese Patent Application (Serial No. JP97-61875) as originally filed

A compound represented by the formula:

wherein R represents a phenyl group, naphthyl group, <u>pyridyl group</u>, furyl group, thienyl group <u>each of which has one or two substituents</u> selected from the group consisting of a hydroxyl group, a lower alkoxy group, <u>a hydroxyl lower alkyl group</u>, and a hydroxyl lower alkenyl group, except that when the phenyl group, naphthyl group, pyridyl group, furyl group, or thienyl group has a lower alkoxy group as a substituent, each of which simultaneously has another substituent selected from the group consisting of a hydroxyl group, a lower alkoxy group, a hydroxyl lower alkyl group and a hydroxyl lower alkenyl group;

m represents an integer of 1 to 3;

G represents a β -D-glucopyranosyl group; and the positions of substitution of the hydroxyl groups on the indolopyrrolocarbazole ring are the 1- and 11-positions, or the 2- and 10-positions,

or a pharmaceutically acceptable salt thereof.

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6	PE STATISMENT D	W A DY	I ICANIT	Filing Date	March 14, 2006	
	STATEMENT B	I API	LICANI	First Named Inventor	Koji Yamada	
1	0 4 2006		,	Group Art Unit	To be determined	
By.	(use es/many sheets as necessary)		Examiner Name	To be determined		
Shee	et 1	of	2	Attorney Docket Number	BY0028P	

U.S. PATENT DOCUMENTS							
Examiner Initials*	U.S. Patent Document Cite No. Number Code		Kind	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
		US 6,703,373		Katsuhisa, et al.	03/09/2004		
		US 4,785,085		Kaneko, et al.	11/15/1988		
		US 5,437,996		Kojiri, et al.	08/01/1995		
		US 5,478,813		Okanishi, et al.	12/26/1995		
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	FOREIGN PATENT DOCUMENTS								
Euromino	C:		Foreign Patent Documen	t		Date of Publication of			
	Cite No.	Office	. Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Cited Document MM-DD-YYYY			
		PCT	WO 2002/036601		Merck & Co., Inc.	05/10/2002			
		PCT	WO 1996/004293		Banyu Pharmaceutical Co., Ltd.	02/15/1996			
		ЉО	JP 6-128283		Banyu Pharmaceutical Co., Ltd.	05/10/1994			
		ЉО	JP 10-245390		Banyu Pharmaceutical Co., Ltd.	09/14/1998			

Examiner Signature	Date Considered		
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^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

				Tatem and Transfer Office, O.B DEFTACTION OF COMMERCE		
Substitute for form 1449R/PTO			COMPLETE IF KNOWN			
INFORMATION DISCLOSURE		Application Number	10/571,861			
TATEMENT DI	7 A D	DI ICANT	Filing Date	March 14, 2006		
STATEMENT BY APPLICANT			First Named Inventor	Koji Yamada		
,		,	Group Art Unit	To be determined		
(use as many sheets as necessary)		Examiner Name	To be determined			
2	of	2	Attorney Docket Number	BY0028P		
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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.			
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Examiner Signature	Date Considered	

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.